K073159 #1/3

Appendix I. 510(k) Summary

JUL 23 2008

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The Assigned 510(k) Number is:_____

1. Applicant Device Information

Trade/Proprietary Name: Trauson Bone Screw
Common Name: Smooth or threaded metallic bone fixation fastener
Classification Name: Screw, fixation, bone
Device Class: II
Product Code: HWC
Regulation Number: 888.3040
Intended Use:
Trauson Bone Screw is indicated for bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation of bones appropriate for the size of the device.

2. Submitter Information

Establishment Registration Name:
TRAUSON (JIANGSU) MEDICAL INSTRUMENT CO., LTD.
31 Houcun Road, Niutang Town
Changzhou, Jiangsu,
CHINA 213163
Phone: +86-757-86280075
Fax: +86-757-86397179

Contact Person of the Submission:
Ms. Diana Hong
Mr. Eric. Chen
Shanghai Mid-link Consulting Co., Ltd.
5300 Playa Vista Drive, Unit 15
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K073159 #2/3

3. Predicate Device

K-number: K060071

Device Name:

Nexa Compression Screw

Device Trade Name:

Nexa Compression Screw

Manufactured by:

Nexa Orthopedics, Inc., (dba Futura Biomedical, LLC)
10675 Sorrento Valley Road, Suite 1 00
San Diego, CA 92121

4. Device Description

The applicant device of Trauson Bone Screw consists of screws made of medic 11 grade 3 16L stainless steel that meet ASTM 138 is intended for fixation of fractures, fusions, or osteotomies of bones of the hand and foot. The screws are Type HA with spherical undersurface of head, shallow, asymmetrical buttress thread, and deep screw head.

The applicant devices are not sterile. No new materials are used in the development of this implant.

5. Test Data

The applicant device material only contains Medic 11 grade 3 16L stainless steel that meets ASTM 138, and the material is medical grade and widely used in the industry which requires no biocompatibility testing.

However, the all conducted Biological Evaluation Tests are in compliance with the standards of ISO 10993, "Biological Evaluation of Medical Devices". The compatibility of all the component material in the finished product was provided.

Bench tests of the applicant device are conducted to determine the Torsional properties, Insertion Torque, Pullout Test, please see the **Appendix 2**, ASTM Test Report

6. Substantially Equivalence

Comparison Analysis:

The Applicant device has the same classification information, intended use, sterilization specifications, performance, biocompatibility, chemical specifications and similar physical and mechanical specifications with the predicate device. The only difference between applicant device and predicate device is some physical specifications variant which is too slight to influence the effectiveness and safety. No new question was raised.

Conclusion:

The applicant device is **Substantially Equivalent (SE)** to the predicate device in terms of Effectiveness and Safety.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 23 2008

Trauson (Jiangsu) Medical Instrument Co., LTD.
% Diana Hong
Lane 999, Ahongshan No. 2 Road
Suite 8D, No. 19
Shanghai, China 200030

Re: K073159
Trade/Device Name: Trauson Bone Screw, Models HA 3.5 and 4.5
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: July 21, 2008
Received: July 22, 2008

Dear Ms. Hong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Appendix II. Indications for Use

510(k) Number: K073159

Device Name: Trauson Bone Screw

Indications for Use:

Trauson Bone Screw is indicated for bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation of bones appropriate for the size of the device.

Prescription Use ___√___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K073159